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Letter Ruling 01-6: Sales Tax Treatment of Certain Clean Room Equipment

August 17, 2001

You request a ruling on behalf of ********** (the "Company"), a manufacturer of high precision reagents used in the pharmaceutical and medical device industries. Company's products are manufactured using "clean room" technology. A "clean room" is an enclosed structure where specialized equipment is used to create a precisely controlled manufacturing environment free from naturally occurring substances that, if left unchecked, would render the semi-finished and raw products unusable.

Company requests a ruling that its purchases of specialized air-handling equipment, controls, and filtration systems used to create and maintain a clean room manufacturing environment are exempt from sales and use tax under G.L. c. 64H, § 6(s). In addition, Company asks for a ruling as to the § 6(s) exemption for related support equipment consisting of the following items: chillers, steam generators, humidifiers, dehumidifiers, probes and other measurement devices, automated deflectors, a standby generator, and specialized ductwork connecting the clean room handling equipment to the clean room.

The Company states that the clean room equipment will be purchased from multiple vendors through the Design/Build contractor for the facility.[1]

STATEMENT OF FACTS

Company is a Massachusetts corporation engaged in the business of researching, developing, manufacturing and marketing *Limulus* amebocyte lysate (LAL) products used in endotoxin testing.[2] Company manufactures an ultra-pure LAL reagent, using organic materials from the *Limulus polyphemus*, otherwise known as the horseshoe crab. The primary application for Company's LAL reagent is the testing of parenteral pharmaceuticals and medical devices that contact blood or cerebral spinal fluid.

Since Company's products will be used to test the products of pharmaceutical and medical device companies for endotoxin contamination, they must be manufactured to be free of detectable contamination themselves. Maintenance of manufacturing conditions that minimize the risk of contamination to Company's LAL products is critical due to the product's exquisite sensitivity to endotoxin. LAL is sensitive to as low as 0.1 trillionth of a gram of endotoxin and spoils if contaminated.

Clean Room Manufacturing

Company's clean room equipment will be used to create a specific manufacturing environment required for the manufacture of Company's products. LAL products are highly susceptible, throughout the manufacturing process, to airborne contaminants and to variations in temperature and humidity. Although the clean room equipment does not itself come into actual physical contact with the items Company produces, the equipment nonetheless is absolutely essential to the production process. Without the sterile and controlled air environment created by clean room equipment, it is impossible to manufacture Company's products.

Ordinary air often has particulate levels in the hundreds of thousands per cubic foot. Controlled air environments demand air cleanliness at different levels, appropriate to different levels of manufacturing requirements.[3] The removal of particles and other contaminants is accomplished through a combination of High Efficiency Particulate Air ("HEPA") filters and associated air handlers. The HEPA filters are constructed to achieve removal efficiencies of 99.97% for particles of a 0.5 micron diameter or more.

The air handlers force air circulation through these filters at a rate sufficient to maintain the required level of cleanliness.

The Company's production activities will occur in three successive rooms, with increasingly stringent cleanliness standards. In the first room, the particulate level cannot exceed 100,000 particles per cubic foot. In the second room, the particulate level cannot exceed 10,000 particles per cubic foot. In the third room, the particulate level cannot exceed 100 particles per cubic foot.

Since the raw material for Company's LAL reagent is organic, excessive temperature renders it unstable. Similarly, excessive humidity promotes the growth of micro-organisms such as biofilms, which in turn contribute to airborne particulates. Humidity is controlled at the level of the air handlers by humidifiers and dehumidifiers, while temperature is regulated through the use of heat exchangers, chillers, and steam generators in the airflow path.

The pressure of the controlled air environment is maintained by the air handlers at a level above that of the surrounding areas in order to prevent any inflow or seepage of contaminated air from outside the clean rooms. Automated deflectors continuously increase or decrease airflow depending on the pressure reading.

Various probes and measurement devices provide continuous feedback to ensure that the required level of cleanliness is being maintained. Specialized ductwork connects the clean room air handling equipment to the clean rooms as part of the overall sealed environment.

It is currently impossible to create an environment that is 100% "clean." Consequently, there is always a residual level of micro-organisms and contaminants present, some of them originating in the raw materials themselves. Provided that these residual contaminants are kept to a *de minimis* level (e.g., 100 particles per cubic foot), they do not have a deleterious effect on the product. The problem is that the micro-organisms in question are alive and will continue to reproduce, a process that, unchecked, would eventually push the level of contaminants beyond those acceptable, *de minimis* limits. By constantly circulating the air through the HEPA filters, the air handling equipment is used to counteract this process by continually sweeping the air and any surfaces clean of these new contaminants. The temperature and humidity controls are used to retard the growth of these micro-organisms (which, in turn, limits the number of new particles in the environment that need to be removed).

The clean rooms are separate and self-contained areas in which the manufacturing process occurs. The activities that occur within the clean rooms begin with the extraction of the raw materials used to produce the LAL reagent and end with the packaging of the final product in the sealed containers in which it is sold. The clean room equipment is not intended, and will not be used, for any other purpose than to create the required manufacturing environment. For example, it will not be used to provide any sort of HVAC service to other parts of the facility. In fact, if the controlled air environment is contaminated with air from other parts of the facility, it will require a temporary shut-down of the "clean room" and a complete recycling of the air in that environment (which will take

approximately 24 hours).

Finally, a standby generator is used to power the clean room equipment in order to maintain the required manufacturing conditions in the event of a power outage.

DISCUSSION

General Laws chapter 64H, § 2 imposes an excise upon sales at retail in the Commonwealth by any vendor of tangible personal property or telecommunications services, unless otherwise exempt. The excise is imposed at the rate of five percent of the gross receipts of the vendor from all such sales. *Id.* General Laws chapter 64I, § 2 imposes an excise upon the storage, use, or other consumption in the Commonwealth of tangible personal property or telecommunications services purchased from any vendor for such use. The excise is imposed at the rate of five percent of the sales price of the property or services. *Id.* General Laws chapter 64I, § 7(b), generally exempts from the use tax any sale that would be exempt from sales tax under chapter 64H.

In relevant part, G. L. c. 64H, § 6(s), provides an exemption from sales tax for sales of "machinery, or replacement parts thereof, used directly and exclusively . . . in an industrial plant in the actual manufacture of tangible personal property to be sold." Section 6(s) provides five definitions of exempt uses of machinery:

> . . . machinery shall be deemed to be used directly and exclusively in the actual manufacture, conversion or processing of tangible personal property to be sold only where such machinery is used solely during a manufacturing, conversion or processing operation [1] to effect a direct and immediate physical change upon the tangible personal property to be sold; [2] to guide or measure a direct and immediate physical change upon such property where such function is an integral and essential part of tuning, verifying or aligning the component parts of such property; or [3] to test or measure such property where such function is an integral part of the production flow or function; used solely [4] to store, transport, convey or handle such property during the manufacturing, converting, or processing operations heretofore specified; or used solely [5] to place such property in the container, package or wrapping in which such property is normally sold to the ultimate consumer thereof.

An additional exemption is contained in § 6(s) for the sale of machinery and replacement parts used "directly and exclusively" in "furnishing of power to an industrial manufacturing plant." Company's purchase of a standby generator to be used to power the clean room equipment in the event of a power outage qualifies for this exemption.

The Supreme Judicial Court defines "machinery" as "any combination of mechanical means designed to work together so as to effect a given end." *Warner Amex Cable v. Board of Assessors*, 396 Mass. 239, 242 (1985). For purposes of the § 6(s) exemption, the Appellate Tax Board has defined "machinery" as:

> a mechanical, electrical or electronic device designed to be used and which is used in manufacturing, converting or processing tangible personal property to be sold. It includes not only the basic unit but also any adjunct or attachment necessary for the basic unit to accomplish its intended function. It also includes all devices used or required to control, regulate or operate a piece of machinery, provided such devices are directly connected with or are an integral part of the machinery and are used exclusively for the purposes mentioned.

*See Western Electric Co, Inc. v. Commissioner of Reve*nue, A.T.B. Docket No. 113779 (1984).[4]

The following items come within either of the above definitions of machinery: clean room air-handling equipment, controls, and filtration systems. Also, the following items of support equipment qualify as machinery: chillers and steam generators (for temperature regulation), humidifiers and dehumidifiers (for humidity control), automated deflectors (to control airflow), probes and measurement devices (to monitor air quality and provide continuous feedback). The specialized ductwork, attached to the clean room equipment and used exclusively to connect it to the clean rooms, qualifies as machinery under the second definition as an "adjunct or attachment necessary for the basic unit [air handling equipment] to accomplish its intended function."[5]

This ruling acknowledges that Company's facility is an industrial plant that manufactures tangible personal property to be sold. Having concluded that the listed items of clean room equipment come within the definition of "machinery," we must then determine whether the items meet the added requirement of being used "directly and exclusively" in "actual manufacture." The Commissioner announced in Technical Information Release 99-16 that any machinery that is used solely in *any one* of the five activities enumerated in § 6(s) is used "directly and exclusively" in the "actual" manufacture of tangible personal property. No additional proof will be required from the taxpayer as to the use "directly and exclusively" or as to the "actual manufacture" of the property. *Id.*

The Supreme Judicial Court has construed the first and second uses listed in § 6(s) in a case involving exhaust, ventilation, waste water treatment systems and air treatment systems used to treat hazardous fumes, dust and contaminates generated by the taxpayer's manufacturing process. *See Commissioner of Revenue v. V.H. Blackinton & Co.,* 420 Mass. 259 (1995). The Court ruled that pollution control equipment whose use in the manufacturing process was required by federal, state, and local environmental laws did not qualify for the § 6(s) exemption, even if viewed as *legally* necessary to the manufacturing process, absent a determination that the equipment "effects any physical change on property to be sold." *Id* at 262.

In *Commissioner of Revenue v. Fashion Affiliates, Inc*., 387 Mass. 543 (1982), the Supreme Judicial Court evaluated the second statutory use in § 6(s). In *Fashion Affiliates*, the Court considered a computer and a series of related machines used to produce paper markers used in tracing dress patterns as part of the process of manufacturing dresses. Factory workers used the paper markers to guide machinery that cut fabric from which dresses were produced. The system was used during a manufacturing operation to guide or measure a direct and immediate physical change upon the material, a function that played an integral and necessary role in producing properly cut portions of the dresses being manufactured. No aspect of the computer system came into direct physical contact with dress fabrics or with knives that cut dress patterns from the fabric. Even so, the system qualified under the second use listed for the § 6(s) exemption: "The physical change upon the material must be immediate and direct, as it is. The definition does not require that the machinery's guidance or measurement be direct or immediate in the sense of physical contact." *Id* at 546.

In Department Directive 87-8, the Department interpreted the first use listed in § 6(s) to exempt air-conditioning equipment that reduced the temperature of ambient air so that plastic a taxpayer was producing for sale would harden to a point where it was saleable. The equipment operated separately from and in addition to normal air-conditioning equipment at the taxpayer's factory and did not come into direct physical contact with materials being produced for sale. In construing the exemption, Directive 87-8 adopts language from *Fashion Affiliates:* "[t]here is . . . no requirement that this physical change be direct or immediate in the sense of physical contact." The key fact was that the air-conditioning equipment caused a physical change to the air that, in turn, caused a physical change to the tangible personal property to be sold.[6]

Applying the relevant authorities to the facts as you state them, Company's clean room machinery (other than the standby generator) falls within the first statutory definition of exempt use in § 6(s) as machinery used "to effect a direct and immediate physical change upon the tangible personal property to be sold."

Company's configuration of clean room machinery operates to effect a direct and immediate physical change upon the tangible personal property to be sold by creating the ultra-clean atmospheric conditions (air substantially free of endotoxin) that must surround the product during all stages of production. The clean room machinery sweeps the work in process with air that is processed to extreme standards, with temperature, moisture and pressure maintained within a limited range and

virtually all particles filtered from the air. Precise monitoring and control of the temperature, humidity, pressure and particle content in the air around all phases of production preserves the purity of raw materials, semi-finished materials and finished LAL reagent. Under the law of *Fashion Affiliates*, although the physical change upon the material must be immediate and direct, as it is, physical contact is not required.[7]

The nonexempt pollution control equipment in *Blackinton* was used to protect human health in compliance with state and federal law. In contrast, Company's configuration of clean room machinery is used in all phases of production to preserve the purity of the tangible personal property to be sold. Company's LAL reagent is used by the pharmaceutical and medical device industries to test their own products for endotoxin. If the reagent itself were contaminated with endotoxin, it would yield false positive results and be totally useless. Keeping highly processed, tightly controlled air flowing around the work in process prevents contamination by micro-organisms or particles bearing endotoxin. Since these contaminants are virtually ubiquitous in ordinary air, it is critical that the product be protected from them at all times. If the clean room machinery did not control the manufacturing environment, Company's product would become contaminated by airborne particles and/or corrupted by changes in temperature and humidity.

Your letter states that the clean room equipment will be solely dedicated to clean room manufacturing operations and that the controlled air environments are separate and self-contained areas in which the manufacturing process occurs. The air handlers supply air-conditioning essential to the manufacturing process, and not a matter of worker comfort. Thus, the clean room equipment is used "solely during a manufacturing, conversion or processing operation to effect a direct and immediate physical change upon the tangible personal property to be sold." G.L. c. 64H, § 6(s) (first use).

CONCLUSION

Company's purchases of certain items of clean room equipment are exempt from sales tax under G.L. c. 64H, § 6(s), as machinery used directly and exclusively in an industrial plant in the actual manufacture of tangible personal property to be sold. Based on the facts stated, the § 6(s) exemption extends to any of the following items that are solely dedicated to clean room manufacturing operations: air-handling equipment, controls, filtration systems, and related support equipment consisting of chillers, steam generators, humidifiers and dehumidifiers, automated deflectors (to control airflow), probes and measurement devices (to monitor air quality and provide continuous feedback), and specialized ductwork (attached to the clean room equipment and used exclusively to connect it to the clean rooms). In addition, Company's purchase of a standby generator is exempt from sales tax under G.L. c. 64H, § 6(s) as machinery used directly and exclusively in the furnishing of power to an industrial manufacturing plant. Finally, under TIR 99-21, the § 6(s) exemption is extended to any purchases of these items by an agent of the Company.

Very truly yours,

/s/Bernard F. Crowley, Jr.

Bernard F. Crowley, Jr.
Acting Commissioner of Revenue

BFC:DMS:adh

LR 01-6

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[1] You conclude that, for purposes of TIR 99-21, the Design/Build contractor will be acting as agent for the Company. Principles for determining whether a party is an agent of a principal have been discussed in a number of Massachusetts decisions. *See, e.g.*, *Araserve, Inc. v. Commissioner of Revenue*, A.T.B. Docket No. 223254 (1998); *Hart and McGinley v. Commissioner of Revenue*, A.T.B. Docket No. 223254 (1998); *Harrison Conference Services of Massachusetts, Inc. v.*

Commissioner of Revenue, 394 Mass. 21 (1985). You have not supplied us with any facts upon which we could make a determination of agency, and you have not asked us to rule on whether, under Massachusetts law, the Design/Build contractor is an agent for the Company. Thus, this ruling does not express any opinion on whether the Design/Build contractor will be acting as agent for the Company.

[2] Endotoxin is a component of the cell wall of gram negative bacteria. Bits of endotoxin break off as bacteria grow and move in their environment. Killed or crushed, bacteria release larger amounts of endotoxin. Endotoxin is constantly shed into the environment on dust, skin flakes, textile fibers, exhalation aerosols, etc., and is not dangerous to humans under normal conditions. However, endotoxin can cause serious negative medical consequences if it is introduced into patients through their blood or cerebrospinal fluid. When endotoxin is detected by blood cells in internal body organs, the immune system is mobilized to combat infection by, *inter alia*, raising body temperature. If body temperature is raised too high, serious illness or death can result.

[3] Typically these are denominated in terms of the maximum number of 0.5 micron, or greater, particulates per cubic foot: *e.g.,* Class 100,000, class 10,000, and class 100.

[4] This definition of machinery is found in two former regulations, Emergency Sales and Use Tax Regulation No. 18, which expired and 830 CMR 16.03, Machinery Exemption, which was repealed in 1986. Although the regulations are no longer in effect, the definition of machinery used therein has been adopted by the Department. *See* Department Directives 88-4 and 88-5.

[5] Also, by way of analogy, *see* Department Directive 86-2 allowing the exemption for solar equipment at G.L. c. 64H, § 6(dd) for the sale of fans and ductwork as components of a solar heating system.

[6] Conversely, the § 6(s) exemption does not apply to sales of machinery used for general ventilation, heating, cooling, climate control or pollution control where such use is not required by the manufacturing process. *See also* Department Directive 87-7 and *Blackinton*, supra.

[7] The Commissioner has previously ruled that clean room machinery is used "directly and exclusively in an industrial plant in the actual manufacture of tangible personal property to be sold" for purposes of the separate but related exemption at G.L. c. 64H, § 6(i). In Letter Ruling 99-16, the issue was whether a taxpayer with a clean room facility met the 75 percent threshold for electrical usage required by the § 6(i) exemption. The taxpayer was a manufacturer of high precision filtration devices and systems used in the pharmaceuticals industry. A significant portion of the electrical usage for the taxpayer's manufacturing functions was attributable to environmental control equipment consisting of humidifiers, dehumidifiers and other clean room machinery. The facts outlined in LR 99-16 state that:

> Clean room machinery creates laminar flow clean air to rinse particles from the surface of the product being manufactured and to remove these particles from the room. This cleansing is a physical change necessary to make specific products usable and saleable.

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